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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,538	12/28/2001	Stephen D. Pacetti	50623.149	3811

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EXAMINER
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MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/040,538	Applicant(s) PACETTI ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-26 and 33-70 is/are pending in the application.
- 4a) Of the above claim(s) 7,12,14,37-40,42,43,47 and 54-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-11,13,15-26,33-36,41,44-46 and 48-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/8/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claims 54-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: original claims are directed to the use of temperature to either inhibit or induce evaporation of solvent from a coating based on the volatility of the solvent. New claims are devoid of these limitations. Furthermore, new claims require the use of a holding fixture.
2. Newly submitted claims 37-40, 42-43, and 47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: examined claims (such as claim 3) were directed to the simultaneous application of composition and gas. The newly-added claims require termination of spraying composition prior to directing the gas or require the spraying and directing to occur in sequence. Simultaneous application and sequential application are distinct species. The new claims even differ from the original form of claim 7 which required only the repetition of applying and directing (but not that applying and directing occur sequentially). Claim 7 has been modified to embody the second species.

Since applicant has received an action on the merits for the originally presented invention and species, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 7, 37-40, 42-43, 47, and 54-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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*As necessitated by amendment, the following new 112 rejections are presented:*

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 13, 16, 23-26, 33, 44-46, 48-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner is unable to find reference to "directly" blowing a gas onto the device. Examiner finds reference to "directing a gas onto" the device, however, Applicant appears to draw a distinction between these two limitations for the purposes of his amendment.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13, 16, 23-26, 33, 44-46, 48-53 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Based on the new matter rejection, Examiner is unable to look to the specification for clarification of the term "directly". Applicant's arguments seem to suggest that directly blowing a gas onto a substrate requires a certain degree of

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closeness or a perceptible amount of wind be felt, such as by sitting close to an air conditioner and feeling the cool air. Therefore, the term "directly" is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Additionally, the phrase "the blowing does not affect the direction of the spray onto the device" is unclear. Any gas blown onto the device will inherently affect the direction of the spray to some degree. The specification states that the direction will only be affected if the gas is blown at higher speeds. Therefore, the claim can be interpreted to require a slower flow of gas. However, Examiner notes that if Applicant defines "directly" blowing to require enough force so that the gas flow can be felt, then the gas flow will be "felt" by the composition being sprayed, which invariably will alter the direction of the spray to some degree.

### ***Claim Rejections - 35 USC § 102***

8. Claims 1-6, 11, 13, 17-19, 21-24, 33-36, 44, 46, and 48-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al. (US 6,395,326).

Examiner maintains the rejection of the previous office action for claims 1-7, 11, 13, 17-19, and 21-24.

As necessitated by amendment, claims 33-36, 44, 46, and 48-53 are added to this rejection for the reasons outlined in the previous office action and below.

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Claim 7 has been withdrawn from this rejection.

It does not appear that Castro's blown gas affects the direction of spray from what is intended. Castro teaches rotation. The coating, gas, temperature and flow are inherently controlled by someone or by machine. Application is simultaneous with blowing the gas. Castro teaches the use of air, the use of atomized spraying, and a composition of polymer and paclitaxel. Gas appears to be blown directly.

***Claim Rejections - 35 USC § 103***

9. Claims 9-10, 15-16, 20, 25-26, 41, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al.

Examiner maintains the rejections of claims 9-10, 15-16, 20, and 25-26 for the reasons outlined in the previous office action.

Examiner adds claims 41 and 45 to this rejection, as necessitated by amendment. The rotation speed is a cause-effective variable and would have been obvious to optimize for the same reasons outlined in the previous office action regarding distance and flow rate. The use of inert gas is obvious for the reasons outlined in the previous office action.

10. Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-49, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (US 6,358,556) in view of You et al. (US 6,407,009).

Examiner maintains the rejection of claims 1-6, 9-11, 13, and 15-26.

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Examiner adds claims 33-36, 41, 44-46, 48-49, 51-53 to this rejection for reasons outlined in the previous office action and/or below.

It does not appear that Ding in view of You's blown gas affects the direction of spray from what is intended. Ding teaches rotation. The coating, gas, temperature and flow are inherently controlled by someone or by machine. Application is simultaneous with blowing the gas. Gas appears to be blown directly. The rotation speed is a cause-effective variable and would have been obvious to optimize for the same reasons outlined in the previous office action regarding distance and flow rate. The use of inert gas is obvious for the reasons outlined in the previous office action.

### ***Response to Arguments***

11. Applicant's arguments filed 3/30/2005 have been fully considered but they are not persuasive.

Applicant argues that Castro's heat conduit with nozzle and orifice used for directing heat onto the stent to dry its coating is not taught to direct heated gas onto the stent. Applicant speculates that a charged, glowing pin may be positioned in the orifice of the nozzle and used for the application of heat.

Examiner notes that conduits are used for conveying fluids, nozzles are used as projecting vents, and orifices are openings. Since Castro does not teach the conveyance and projection of a warm liquid (as such would wet, not dry the coating), it is immediately clear to an ordinary artisan that Castro is conveying and projecting a gas. A heated pin would not require an elaborate conduit, nozzle or orifice to provide heat.

Heat supplied in the form of a gas, via a conduit, nozzle, and orifice (for example, like with a hair dryer) to dry a coated stent would have been immediately envisioned by one of ordinary skill in the art viewing this reference. A heated fluid that is not a liquid, must be a gas.

Additionally, even the heated pin envisioned by Applicant would heat the surrounding air which would be directed onto the stent to accomplish the task of heating the stent.

Applicant argues that Castro and Ding in view of You do not teach temperature adjustment based on vapor pressure of the solvent, wherein it is inhibited if the vapor pressure is above 17.54 Torr and induced if the vapor pressure is less than 17.54 Torr. Examiner disagrees and refers Applicant to the very explicit showing made by Examiner Jolley. The claim requires one of two scenarios based on vapor pressure. For example, Castro teaches the scenario in which the solvent has a vapor pressure lower than 17.54 Torr and uses a temperature to induce evaporation. The claim limitations have been met.

Applicant argues that You fails to teach "directly" blowing the gas and compares You to the indirect cooling felt in an air conditioned room.

Based on 112 rejections made above, Examiner does not feel Applicant has basis for such a claim limitation, nor for arguments made. The gas of You is intended to affect the substrate. It is directed onto the substrate. The specification does not provide requirements for the path the gas must take, the speed the gas must possess, or the

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distance the dispenser must be from the substrate in order to meet the limitation of "directly:".

Applicant argues that You is not in the field of endeavor of Applicant (or, presumably, Ding) and argues that Examiner has broadened that field to any deposition of coating. Examiner disagrees.

Ding, You, and Applicant are all three concerned with spraying a solvenated polymer coating onto a rotating substrate, with the desire to control evaporation.

Applicant argues that You is not pertinent to the problem with which the invention was concerned and requires Examiner to explain why a person in the stent art would look to the semiconductor art. Additionally, Applicant argues there is no motivation to combine the Ding and You references.

Ding is concerned with forming a conformal, uniform coating by spraying on a rotating substrate and evaporating the solvent. You is concerned with forming a uniform coating by spraying on a rotating substrate and controlling the evaporation rate of the solvent. By controlling the evaporation rate, You can avoid non-uniform build-up of materials to provide a more even coating (col. 6, line 60-Col. 7, line 10). For these reasons and those provided by Examiner in the previous office action, the references may be combined. One practicing Ding would look to the prior art for accomplishing uniform coating when evaporating solvents. The teachings of You would provide a mechanism for controlling evaporation rates to achieve such uniformity. Just like the Ding and You

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references, Applicant endeavors to solve a similar problem: preventing the liquid coating composition from collecting, clumping, or pooling (page 2 of the instant specification). Applicant and You are both concerned with preventing build-up of coating materials so as to produce uniform coatings on rotating substrates, sprayed with solvenated polymers.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Tuesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Michener  
AU 1762  
Primary Examiner  
June 25, 2005